IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KISSEI PHARMACEUTICAL CO., LTD., WATSON LABORATORIES, INC. and ACTAVIS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SANDOZ INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Kissei Pharmaceutical Co., Ltd., Watson Laboratories, Inc., and Actavis Inc., (collectively "Plaintiffs"), by and through their undersigned counsel, bring this Complaint for patent infringement against Defendant Sandoz Inc. ("Sandoz" or "Defendant") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement. This action relates to an Abbreviated New Drug Application ("ANDA") submitted by and/or for the benefit of Sandoz with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Plaintiffs' RAPAFLO® capsules, 4 mg and 8 mg, that are sold in the United States.

THE PARTIES

2. Plaintiff Kissei Pharmaceutical Co., Ltd. ("Kissei") is a Japanese corporation, having its principal place of business at 19-48, Yoshino, Matsumoto City, Nagano Prefecture 399-8710, Japan. Kissei is an R&D-oriented pharmaceutical company that contributes to the health of people around the world through innovative drug products. Kissei is the owner and assignee of U.S. Patent No. 5,387,603 ("the '603 patent").

3. Actavis, Inc. ("Actavis") is a corporation organized and existing under the laws of the State of Nevada with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey. Actavis is the exclusive licensee of the '603 patent.

4. Watson Laboratories, Inc. ("Watson") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 577 Chipeta Way, Salt Lake City, Utah 84108. Watson is a wholly-owned subsidiary of Actavis, and is the registered holder of approved New Drug Application No. 22-206.

5. On information and belief, Defendant Sandoz is a corporation organized under the laws of Colorado, having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540. On information and belief, Sandoz develops and markets a wide range of generic drug products and regularly conducts business throughout the United States, including in the State of Delaware.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America, 35 U.S.C. §§ 1, *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a).

7. On information and belief, Sandoz is subject to personal jurisdiction in this District by virtue of its presence and activities in the State of Delaware, and by having systematic and continuous contacts with the State of Delaware so as to reasonably allow personal jurisdiction to be exercised over it.

8. On information and belief, Sandoz is registered to distribute drugs in the State of Delaware, and is in the business of making and selling generic pharmaceutical products, which Sandoz distributes in the State of Delaware and throughout the United States.

9. Sandoz is registered with the Delaware Board of Pharmacy, pursuant to 24 Del. C. § 2540, as a licensed "Distributor/Manufacturer CSR" (License No. DS0131) and "Pharmacy-Wholesale" (License A4-0000260). Sandoz admitted this in its Answer in *Cephalon v. Sandoz*, C.A. No. 12-248 (D. Del. Mar. 23, 2012).

10. Additionally, personal jurisdiction over Sandoz is proper because it has previously submitted to jurisdiction in this Court, and has availed itself of the jurisdiction of this Court by asserting counterclaims in lawsuits pending in this district.

11. Sandoz has admitted or consented to jurisdiction (for purposes of litigation) and filed counterclaims in, for example, *Cephalon v. Sandoz*, C.A. No. 12-248 (D. Del. Mar. 23, 2012); *Abbott v. Sandoz*, C.A. No. 12-103 (D. Del. Apr. 9, 2012); *GlaxoSmithKline v. Sandoz*, C.A. No. 11-1284 (D. Del. Mar. 5, 2012); *Pfizer v. Sandoz*, C.A. No. 11-1252 (D. Del. Mar. 8, 2012); *Abbott v. Sandoz*, C.A. No. 11-424 (D. Del. Nov. 14, 2011); *Abbott v. Sandoz Inc.*, C.A. No. 11-145 (D. Del. May 13, 2011); and *Research Foundation of State University of New York et al v. Sandoz Inc.*, C.A. No. 11-162 (D. Del. Apr. 18, 2011).

12. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FACTUAL BACKGROUND

A. The '603 Patent

13. On February 7, 1995, the United States Patent and Trademark Office duly and lawfully issued the '603 patent, entitled "1,5,7-Trisubstituted Indoline Compounds and Salts

Thereof" to inventors Makio Kitazawa, Masaaki Ban, Kosuke Okazaki, Motoyasu Ozawa, Toshikazu Yazaki, and Ryoichi Yamagishi. Kissei is the assignee of the '603 patent. A true and accurate copy of the '603 patent is attached as Exhibit A to this Complaint.

14. The '603 patent claims, *inter alia*, the silodosin compound (the active ingredient in RAPAFLO®), a pharmaceutical composition of silodosin, and a method for the treatment of dysuria by administering to a mammal or a human a therapeutically effective amount of silodosin.

B. RAPAFLO® Drug Product

15. Plaintiff Watson is the registered holder of New Drug Application No. 22-206 for RAPAFLO® capsules, 4 mg and 8 mg, which contain silodosin as the active ingredient. The FDA approved NDA No. 22-206 on October 8, 2008.

16. RAPAFLO® capsules, 4 mg and 8 mg, are indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH), and are marketed and sold in the United States by a subsidiary of Actavis.

17. The '603 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (published by the FDA and commonly known as the "Orange Book") with respect to RAPAFLO® capsules, 4 mg and 8 mg dosage forms.

C. Infringement by Sandoz

18. On information and belief, Sandoz has submitted ANDA No. 204726 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The ANDA seeks approval to engage in the commercial manufacture, use, and sale of silodosin capsules, 4 mg and 8 mg ("Sandoz's ANDA Products"), as a generic version of RAPAFLO®, before the expiration of the '603 patent.

19. Upon information and belief, Sandoz's ANDA No. 204726 contains information to show that Sandoz's ANDA Products (a) are bioequivalent to RAPAFLO® 4 mg and 8 mg capsules, (b) have the same active ingredient as RAPAFLO® 4 mg and 8 mg capsules, (c) have the same route of administration, dosage form, and strength as RAPAFLO® 4 mg and 8 mg capsules, and (d) have the same, or substantially the same, proposed labeling as RAPAFLO® 4 mg and 8 mg capsules.

20. By letter dated May 7, 2013 (the "Notice Letter"), purporting to be a "Notice of Certification Under 21 U.S.C. § 355(j)(2)(B) (§ 505(j)(2)(B) of Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95," Sandoz notified Kissei, Watson and Actavis that it had submitted ANDA No. 204726 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of Sandoz's ANDA Products, which are generic versions of RAPAFLO® 4 mg and 8 mg capsules, prior to the expiration of the '603 patent.

21. Kissei did not receive the Notice Letter until May 8, 2013.

22. Actavis did not receive the Notice Letter until on or about May 8, 2013.

23. Watson did not receive the Notice Letter until on or about May 8, 2013.

24. The Notice Letter stated that Sandoz included in its ANDA No. 204726, a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the '603 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's ANDA Products.

25. The Notice Letter alleges that the '603 patent is invalid, unenforceable, and/or will not be infringed by "the manufacture, use, importation, sale or offer for sale" of Sandoz's ANDA Products, but does not provide any valid basis for these allegations.

26. Sandoz's submission of ANDA No. 204726 to the FDA constitutes infringement of the '603 patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale, or import of Sandoz's ANDA Products into the United States would infringe the '603 patent under 35 U.S.C. § 271(a)-(c).

COUNT I
(Patent Infringement of U.S. Patent No. 5,387,603)

27. Plaintiffs expressly incorporate by reference and reallege paragraphs 1-26, as if fully set forth herein.

28. Upon information and belief, Sandoz's ANDA Products, together with their package inserts, and their use infringe one or more claims of the '603 patent.

29. Upon information and belief, when Sandoz filed ANDA No. 204726, it was aware of the '603 patent and that the filing of its ANDA with the request for its approval prior to the expiration of the '603 patent was an act of infringement.

30. Sandoz was aware of the existence of the '603 patent at least as of the date it sent the May 7, 2013 Notice Letter. On information and belief, Sandoz has the specific intent to induce direct infringement of one or more claims of the '603 patent at least by resellers, pharmacies, health care professionals and end users of Sandoz's ANDA Products.

31. Upon information and belief, Sandoz's submission of ANDA No. 204726 for the purposes of obtaining approval to engage in the commercial manufacture, use and sale of Sandoz's ANDA Products, prior to the expiration of the '603 patent, is an act of infringement of one or more claims of the '603 patent under 35 U.S.C. § 271(e)(2)(A).

32. Unless enjoined by this Court, upon FDA approval of ANDA No. 204726, Sandoz will infringe the '603 patent under 35 U.S.C. §271(a) by making, using, offering to sell, importing, and/or selling Sandoz's ANDA Products in the United States.

33. Unless enjoined by this Court, upon FDA approval of ANDA No. 204726, Sandoz will induce infringement of the '603 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Sandoz's ANDA Products in the United States. On information and belief, upon FDA approval of ANDA No. 204726, Sandoz will intentionally encourage acts of direct infringement with knowledge of the '603 patent and knowledge that its acts are encouraging infringement.

34. Unless enjoined by this Court, upon FDA approval of ANDA No. 204726, Sandoz will contributorily infringe the '603 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Sandoz's ANDA Products in the United States. On information and belief, Sandoz has had and continues to have knowledge that Sandoz's ANDA Products are especially adapted for a use that infringes the '603 patent and that there is no substantial non-infringing use for Sandoz's ANDA Products.

35. Unless Sandoz is enjoined from infringing the '603 patent, Plaintiffs will suffer irreparable harm for which they have no adequate remedy at law, including irreparable harm within the State of Delaware and this Judicial District.

COUNT II
(Declaratory Judgment as to U.S. Patent No. 5,387,603)

36. Plaintiffs expressly incorporate by reference and reallege paragraphs 1-35, as if fully set forth herein.

37. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

38. Upon information and belief, Sandoz has made, and will continue to make, substantial preparation in the United States to commercially manufacture, use, sell, offer to sell, and/or import the Sandoz's ANDA Products prior to expiration of the '603 patent.

39. Upon information and belief, Sandoz intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's ANDA Products immediately and imminently upon final FDA approval of ANDA No. 204726.

40. Upon information and belief, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), Sandoz's commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '603 patent.

41. Upon information and belief, Sandoz's infringing commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's ANDA Products set forth herein will begin following FDA approval of ANDA No. 204726.

42. Upon information and belief, Sandoz has been aware of the existence of the '603 patent, and has no reasonable basis for believing that the commercial manufacture, use, offer for sale, sale and/or importation into the United States of Sandoz's ANDA Products will not infringe, contribute to the infringement thereof, and/or induce the infringement of the '603 patent, thus rendering this case "exceptional," as that term is set forth in 35 U.S.C. § 285.

43. Upon information and belief, Sandoz maintains, and Plaintiffs deny, that the '603 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's ANDA Products. Accordingly, there is a real, substantial, and continuing justiciable case or controversy between Plaintiffs and Sandoz regarding whether Sandoz's commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz' ANDA Products according to ANDA No. 204726 will infringe one or more claims of the '603 patent. Plaintiffs are thus entitled to a

declaration that Sandoz's commercial manufacture, use, sale, offer for sale, and importation into the United States of Sandoz's ANDA Products according to ANDA No. 204726 will infringe one or more claims of the '603 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the '603 patent is valid and enforceable;

B. A judgment that, under 35 U.S.C. § 271(e)(2)(A), Sandoz's submission to the FDA of ANDA No. 204726 to obtain approval for the commercial manufacture, use, and sale of Sandoz's ANDA Products before the expiration date of the '603 patent was an act of infringement of the '603 patent;

C. A judgment that Sandoz has infringed one or more claims of the '603 patent;

D. A declaration that Sandoz's commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's ANDA Products would infringe one or more claims of the '603 patent;

E. A judgment that Sandoz's infringement of the '603 patent has been willful and deliberate;

F. A determination, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date for approval of Sandoz's ANDA No. 204726, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), be a date that is not earlier than the expiration of the '603 patent and any additional periods of exclusivity;

G. An order preliminarily and permanently enjoining Sandoz and its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities

and all other persons acting in concert, participation, or in privity with them, and their successors or assigns, from infringing the '603 patent;

H. A judgment that this is an exceptional case and awarding Kissei, Watson, and Actavis their attorney fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285;

I. Awarding costs and expenses in this action; and

J. Such other and further relief as this Court may deem just and proper.

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